

To: Beck, Nancy[Beck.Nancy@epa.gov]
From: Jain, Komal
Sent: Fri 8/4/2017 6:45:12 PM
Subject: RE: hiring?

He would certainly consider it.

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
Sent: Friday, August 4, 2017 2:38 PM
To: Jain, Komal <Komal_Jain@americanchemistry.com>
Subject: RE: hiring?

Hey Komal,

Would he take a political position?

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Ex. 6 - Personal Privacy

From: Jain, Komal [mailto:Komal_Jain@americanchemistry.com]
Sent: Friday, August 4, 2017 2:35 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: hiring?

Hi Nancy,

I hope you are doing well. Busy for sure! I'd love to catch up whenever you can clear your calendar for lunch or a cocktail.

I heard through Seth Goldberg that you may be hiring for several positions. I'm not inquiring for myself, but for my husband Craig who has been in the environmental arena for a long time. In fact, he is a former EPA employee; he was with the Energy Star program for several years. He recently left Toshiba where he ran its environmental affairs program for the Americas for 10+ years. He's looking for senior level position in a policy/management role (not a scientist). Anything come to mind? I can shoot his CV over if there is a possibility.

Thanks! And, Happy Friday.

All the best,

Komal

Komal K. Jain, J.D. | American Chemistry Council

Senior Director, Chemical Products & Technology Division

komal_jain@americanchemistry.com

700 2nd Street, NE | Washington, DC | 20002

Ex. 6 - Personal Privacy

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To: Beck, Nancy[Beck.Nancy@epa.gov]
From: Jain, Komal
Sent: Fri 8/4/2017 6:34:47 PM
Subject: hiring?

Hi Nancy,

I hope you are doing well. Busy for sure! I'd love to catch up whenever you can clear your calendar for lunch or a cocktail.

I heard through Seth Goldberg that you may be hiring for several positions. I'm not inquiring for myself, but for my husband Craig who has been in the environmental arena for a long time. In fact, he is a former EPA employee; he was with the Energy Star program for several years. He recently left Toshiba where he ran its environmental affairs program for the Americas for 10+ years. He's looking for senior level position in a policy/management role (not a scientist). Anything come to mind? I can shoot his CV over if there is a possibility.

Thanks! And, Happy Friday.

All the best,

Komal

Komal K. Jain, J.D. | American Chemistry Council

Senior Director, Chemical Products & Technology Division

komal_jain@americanchemistry.com

700 2nd Street, NE | Washington, DC | 20002

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To: Beck, Nancy[Beck.Nancy@epa.gov]
From: Schmit, Ryan
Sent: Mon 6/5/2017 11:26:35 PM
Subject: RE: In Print---1,4-Dioxane Publication

Will do.

From: Beck, Nancy
Sent: Monday, June 05, 2017 6:12 PM
To: Schmit, Ryan <schmit.ryan@epa.gov>
Cc: Cleland-Hamnett, Wendy <Cleland-Hamnett.Wendy@epa.gov>
Subject: FW: In Print---1,4-Dioxane Publication

Ryan,

Can you get this to the right folks?

Thanks!

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Ex. 6 - Personal Privacy

From: Dourson, Michael (doursoml) [<mailto:doursoml@ucmail.uc.edu>]
Sent: Monday, June 5, 2017 6:09 PM
To: Akihiko Hirose <akihikoh@dranihs.net>; rhryuichihasegawa08@gmail.com; 'Michael L. Caldwell' <MCaldwell@zacfirm.com>; Beck, Nancy <Beck.Nancy@epa.gov>; Birchfield, Norman <Birchfield.Norman@epa.gov>; yamazaki <k-yamazaki@jisha.or.jp>; kmdilwali@intsci.com; 'Michael L. Caldwell' <MCaldwell@zacfirm.com>; Pierre_Therriault@hc-sc.gc.ca; Richard Charron <Richard.Charron@hc-sc.gc.ca>; Sams, Reeder

<Sams.Reeder@epa.gov>; mhoneycu@tceq.state.tx.us; Deshpande, Satish (MOECC)
<Satish.Deshpande@ontario.ca>; sarah.labib@canada.ca; Shannon Ethridge
<sethridg@tceq.state.tx.us>; Barbara Sassi <barbara.sassi@health.mo.gov>;
dennis.wambuguh@health.mo.gov; Chris Prucha <cprucha@wm.com>; h-kano@jisha.or.jp;
Maier, Michael (maierma) <maierma@ucmail.uc.edu>; t-kasai@jisha.or.jp;
sethridg@tceq.state.tx.us; Robert Maronpot <maronpot@me.com>; Whalan, John
<Whalan.John@epa.gov>; James E. Klaunig <jklauni@indiana.edu>; Jayne Wright
<jayne@jaynewright.co.uk>; Nadine Weinberg <nadine.weinberg@erm.com>; Garoutte,
Jonathan <Jonathan.Garoutte@health.mo.gov>; flagac@michigan.gov;
Joseph.Haney@tceq.texas.gov; Phelka, Amanda <aphelka@nsf.org>; jenglish@nsf.org; Laessig,
Susan <Laessig.Susan@epa.gov>; Herbert, Ron (NIH/NIEHS) [E] <herbert@niehs.nih.gov>;
oono-yurie@mhlw.go.jp; toxpathmcc <toxpathmcc@bellsouth.net>;
Jeff.Wenzel@health.mo.gov; Maria Hegstad <mhegstad@iwpnews.com>; Doug Wolf
<Wolf.Doug@epamail.epa.gov>; helen.goeden@state.mn.us; James.kelly@state.mn.us; Franz,
Christina <Christina_Franz@americanchemistry.com>; Kylie Brockenfelt <KBrockenfelt@epl-
inc.com>; riesd@michigan.gov; 'Sager, Shawn' <Shawn.Sager@arcadis.com>; HOWARD,
WILLIAM B GS-13 USAF AFMC AFCEC/CZTE <william.howard.40@us.af.mil>; Hamlin,
Mel (NIH/NIEHS) [C] (hamlin@niehs.nih.gov) <hamlin@niehs.nih.gov>; ruckner@rx.uga.edu;
Harvey Clewell <HClewell@thehamner.org>; david_dorman@ncsu.edu; fjmiller@nc.rr.com;
rpsharma@uga.edu; Vandenberg, John <Vandenberg.John@epa.gov>
Cc: Jeri.Higginbotham@ky.gov; jcrum@hampmathews.com; burleighflayer@ppg.com; Nance,
Patricia (nancepm) <nancepm@ucmail.uc.edu>; 'Forsberg, Norman'
<Norman.Forsberg@arcadis.com>; 'Mark Lafranco' <Mark.Lafranco@erm.com>; Reichard,
John (reichajf) <reichajf@ucmail.uc.edu>
Subject: In Print---1,4-Dioxane Publication

Dear Colleagues

On behalf of the authors, I am pleased to let you know that our publication is now in print as shown below. The paper was developed under the umbrella of the Alliance for Risk Assessment (ARA), and is open access thanks to Norm Forsberg and his company Arcadis. Please feel free to share this paper as needed.

Cheers!

Michael Dourson

— Risk Science Center (formerly TERA Center) sponsors the International Toxicity Estimates for Risk (ITER) database of risk assessment values on Toxnet: <http://toxnet.nlm.nih.gov/>



From: RSS Feed via IFTTT <weeklydigest@ifttt.com>

Date: Monday, June 5, 2017 at 8:14 AM

To: Michael Dourson <doursoml@ucmail.uc.edu>

Subject: Weekly Digest: If new feed item

from <http://rss.sciencedirect.com/publication/science/02732300>, then add to weekly digest sent to michael.dourson@uc.edu on (7 items)

Update: Mode of action (MOA) for liver tumors induced by oral exposure to 1,4-dioxane

Publication date: August 2017

Source: Regulatory Toxicology and Pharmacology, Volume 88

Author(s): Michael L. Dourson, Jeri Higginbotham, Jeff Crum, Heather Burleigh-Flayer, Patricia Nance, Norman D. Forsberg, Mark Lafranconi, John Reichard

Previous work has shown that the weight of evidence supports the hypothesis that 1,4-dioxane causes liver tumors in rodents through cytotoxicity and subsequent regenerative hyperplasia. Questions regarding a lack of concordant findings for this mode of action (MOA) in mice have not been resolved, however. In the current work, a reanalysis of data from two chronic mouse cancer bioassays on 1,4-dioxane, one 13-week mouse study, seven rat cancer bioassays, coupled with other data such as 1,4-dioxane's negative mutagenicity, its lack of up-regulated DNA repair, and the appearance of liver tumors with a high background incidence, support the conclusion that rodent liver tumors, including those in mice, are evoked by a regenerative hyperplasia MOA. The initiating event for this MOA is metabolic saturation of 1,4-dioxane. Above metabolic saturation, higher doses of the parent compound cause an ever increasing toxicity in the rodent liver as evidenced by higher blood levels of enzymes indicative of liver cell damage and associated histopathology that occurs in a dose and time related manner. Importantly, alternative modes of action can be excluded. The observed liver toxicity has a threshold in the dose scale at or below levels that saturate metabolism, and generally in the range of 9.6–42 mg/kg-day for rats and 57 to

66 mg/kg-day for mice. It follows that threshold approaches to the assessment of this chemical's toxicity are supported by the non-mutagenic, metabolic saturation kinetics, and cytotoxicity-generated regenerative repair information available for 1,4-dioxane promoted rodent liver tumors.

via ScienceDirect Publication: Regulatory Toxicology and Pharmacology <http://ift.tt/2r6ix2E> May 30, 2017 at 02:02AM

via RSS

Feed <http://rss.sciencedirect.com/action/redirectFile?&zone=main&Activity=feed&usageType=outward>

From: Michael Dourson <doursoml@ucmail.uc.edu>

Date: Thursday, February 23, 2017 at 2:28 PM

To: Akihiko Hirose <akihikoh@dranihs.net>, "rhryuichihasegawa08@gmail.com" <rhryuichihasegawa08@gmail.com>, "Michael L. Caldwell" <MCaldwell@zacfirm.com>, "Beck, Nancy" <Nancy_Beck@americanchemistry.com>, "Birchfield, Norman" <Birchfield.Norman@epa.gov>, yamazaki <k-yamazaki@jisha.or.jp>, "kmdilwali@intsci.com" <kmdilwali@intsci.com>, "Michael L. Caldwell" <MCaldwell@zacfirm.com>, "Pierre Therriault@hc-sc.gc.ca" <Pierre_Therriault@hc-sc.gc.ca>, Richard Charron <Richard.Charron@hc-sc.gc.ca>, "Sams, Reeder" <Sams.Reeder@epa.gov>, Michael Honeycutt <MHoneycu@tceq.state.tx.us>, "Deshpande, Satish (MOECC)" <Satish.Deshpande@ontario.ca>, "Labib, Sarah (HC/SC)" <sarah.labib@canada.ca>, Shannon Ethridge <sethridg@tceq.state.tx.us>, Barbara Sassi <barbara.sassi@health.mo.gov>, Dennis Wambuguh <dennis.wambuguh@health.mo.gov>, Chris Prucha <cprucha@wm.com>, "h-kano@jisha.or.jp" <h-kano@jisha.or.jp>, Andy Maier <maierma@ucmail.uc.edu>, "t-kasai@jisha.or.jp" <t-kasai@jisha.or.jp>, "sethridg@tceq.state.tx.us" <sethridg@tceq.state.tx.us>, Robert Maronpot <maronpot@me.com>, "Whalan, John" <Whalan.John@epa.gov>, "Klaunig, James E." <jklauni@indiana.edu>, Jayne Wright <jayne@jaynewright.co.uk>, Nadine Weinberg <nadine.weinberg@erm.com>, "Garoutte, Jonathan" <Jonathan.Garoutte@health.mo.gov>, "Flaga, Christine (DEQ)" <FLAGAC@michigan.gov>, "Joseph.Haney@tceq.texas.gov" <Joseph.Haney@tceq.texas.gov>, "Phelka, Amanda" <aphelka@nsf.org>, "English, Joanne Caroline" <jenglish@nsf.org>, "Laessig, Susan" <Laessig.Susan@epa.gov>, "Herbert, Ron (NIH/NIEHS) [E]" <herbert@niehs.nih.gov>, "oono-yurie@mhlw.go.jp" <oono-yurie@mhlw.go.jp>, toxpathmcc <toxpathmcc@bellsouth.net>, "Jeff.Wenzel@health.mo.gov" <Jeff.Wenzel@health.mo.gov>, Maria Hegstad <mhegstad@iwpnews.com>, Doug Wolf <Wolf.Doug@epamail.epa.gov>, "Goeden, Helen (MDH)" <Helen.Goeden@state.mn.us>, "Kelly, James (MDH)"

<james.kelly@state.mn.us>, "Franz, Christina" <Christina_Franz@americanchemistry.com>, Kylie Brockenfelt <KBrockenfelt@epl-inc.com>, "Ries, Divinia (DEQ)" <RIESD@michigan.gov>, "Sager, Shawn" <Shawn.Sager@arcadis.com>, "HOWARD, WILLIAM B GS-13 USAF AFMC AFCEC/CZTE" <william.howard.40@us.af.mil>, "Hamlin, Mel (NIH/NIEHS) [C]" (hamlin@niehs.nih.gov) <hamlin@niehs.nih.gov>, "ruckner@rx.uga.edu" <ruckner@rx.uga.edu>, Harvey Clewell <HClewell@thehamner.org>, "david_dorman@ncsu.edu" <david_dorman@ncsu.edu>, "fjmiller@nc.rr.com" <fjmiller@nc.rr.com>, "rpsharma@uga.edu" <rpsharma@uga.edu>, John Vandenberg <Vandenberg.John@epamail.epa.gov>
Cc: "Higginbotham, Jeri" (EEC) <Jeri.Higginbotham@ky.gov>, "jcrum@hampmathews.com" <jcrum@hampmathews.com>, "Burleigh-Flayer, Heather" <burleighflayer@ppg.com>, Patricia Nance <nancepm@ucmail.uc.edu>, "Forsberg, Norman" <Norman.Forsberg@arcadis.com>, 'Mark Lafronconi' <Mark.Lafronconi@erm.com>
Subject: Accepted 1,4-Dioxane Publication

Dear Colleagues

On behalf of the authors listed in the CC section of this email, it gives me great pleasure to state that a manuscript entitled "Update: Mode of Action (MOA) for Liver Tumors Induced by Oral Exposure to 1,4-Dioxane" has been accepted by Regulatory Toxicology and Pharmacology. An abstract is found below.

This work was conducted under the auspices of the Alliance for Risk Assessment (*ARA*), and involved multiple groups acting collaboratively. Updates of this accepted text prior to it being published will be posted on the Alliance for Risk Assessment (*ARA*) website, specifically, <http://allianceforrisk.org/14-dioxane-analysis>.

Please feel free to let your colleagues know as well.

Sincerely,



Michael L. Dourson, Ph.D., DABT, FATS, FSRA
Professor

Risk Science Center (formerly TERA)

Department of Environmental Health
University of Cincinnati, College of Medicine
160 Panzeca Way
Cincinnati OH 45267-0056

Ex. 6 - Personal Privacy

<http://eh.uc.edu/tera/>



Abstract

Previous scientific studies show that the weight of evidence supports the hypothesis that 1,4-dioxane causes liver tumors in rodents through cytotoxicity and subsequent regenerative hyperplasia. Questions regarding a lack of concordant findings for this mode of action (MOA) in mice have not been resolved, however. In the current work, a reanalysis of data from two chronic mouse cancer bioassays on 1,4-dioxane, one 13-week mouse study, seven rat cancer bioassays, coupled with other data demonstrating negative mutagenicity, lack of up-regulated DNA repair, and the appearance of liver tumors with a high background incidence, support the conclusion that rodent liver tumors, including those in mice, are evoked by a regenerative hyperplasia MOA. The initiating event for this MOA is metabolic saturation of 1,4-dioxane. Above metabolic saturation, higher doses of the parent compound cause an ever increasing toxicity in the rodent liver as evidenced by higher blood levels of enzymes indicative of liver cell damage and associated histopathology that occurs in a dose and time related manner. Importantly, alternative modes of action can be excluded. The observed liver toxicity has a threshold in the dose scale at or below levels that saturate metabolism, and generally in the range of 9.6 to 42 mg/kg-day for rats and 57 to 66 mg/kg-day for mice. It follows that threshold approaches to the assessment of this chemical's toxicity are supported by the non-mutagenic, metabolic saturation kinetics, and cytotoxicity-generated regenerative repair information available for 1,4-dioxane promoted rodent liver tumors.

From: eesserver@eesmail.elsevier.com [mailto:eesserver@eesmail.elsevier.com]
Sent: Thursday, February 23, 2017 10:33 AM
To: Nance, Patricia (nancepm) <nancepm@ucmail.uc.edu>; pnance1972@gmail.com
Subject: RTP-16-335R2: Final Decision

Ms. No.: RTP-16-335R2

Title: Update: Mode of Action (MOA) for Liver Tumors Induced by Oral Exposure to 1,4-Dioxane

Corresponding Author: Ms. Patricia Nance

Authors: Michael Dourson; Jeri Higginbotham; Jeff Crum; Heather Burleigh-Flayer; Norman Forsberg; Mark Lafranconi

Dear Ms. Nance,

Congratulations. I am pleased to inform you that your manuscript, referenced above, has been accepted for publication in Regulatory Toxicology and Pharmacology.

Many thanks for this paper. We look forward to the submission of your future manuscripts to Regulatory Toxicology and Pharmacology.

Your accepted manuscript will now be transferred to our production department and work will begin on creation of the proof. If we need any additional information to create the proof, we will let you know. If not, you will be contacted again in the next few days with a request to approve the proof and to complete a number of online forms that are required for publication.

When your paper is published on ScienceDirect, you want to make sure it gets the attention it deserves. To help you get your message across, Elsevier has developed a new, free service called AudioSlides: brief, webcast-style presentations that are shown (publicly available) next to your published article. This format gives you the opportunity to explain your research in your own words and attract interest. You will receive an invitation email to create an AudioSlides presentation shortly. For more information and examples, please visit <http://www.elsevier.com/audioslides>.

With kind regards,

Dr. Gio Batta Gori, Editor-in-Chief
Regulatory Toxicology and Pharmacology
E-mail: rtp@elsevier.com

To: Beck, Nancy[Beck.Nancy@epa.gov]
From: Goldstein, Bernard D
Sent: Mon 5/22/2017 7:51:50 PM
Subject: RE: Follow-up on SRA Session

Sorry to be unclear. I do need names for the submission, but do not need your participation in the preparation of the abstract. I apologize, as I should have realized that this might be a problem for you

Needless to say, you could withdraw at any time.

Bernie

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
Sent: Monday, May 22, 2017 7:42 AM
To: Goldstein, Bernard D <bdgold@pitt.edu>
Subject: RE: Follow-up on SRA Session

Bernie,

As I am recused from interactions with ACC, it's a bit awkward for me to be planning a session with them.

As you said you don't need names just yet for the submission, why don't you just move ahead without me and let's circle back in the fall to see if it makes sense for me to join the panel.

Regards,

Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Ex. 6 - Personal Privacy

From: Goldstein, Bernard D [<mailto:bdgold@pitt.edu>]
Sent: Monday, May 22, 2017 5:24 AM
To: White, Kimberly <Kimberly_White@americanchemistry.com>
Cc: Rick_Becker@americanchemistry.com; Joe Arvai <jarvai@umich.edu>; Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: Follow-up on SRA Session

Hi Kimberly

Your changes are OK with me, but I have added a few words (“and decreasing the likelihood of the involvement of knowledgeable academic scientists in EPA review processes”) to reflect the substantial concern of the academic community about the following provision in the SAB Act. (I also think that the provision is short-sighted from an industry perspective).

“(H) a Board member shall have no current grants or contracts from the Environmental Protection Agency

and shall not apply for a grant or contract for 3 years following the end of that member’s service on the Board.”

There is also other language in the Act which could be interpreted as the above provision being applicable to not only full SAB Board membership, but to the members of any EPA review process of any hazard or risk assessment

Let me know if the new language is acceptable to you. I'm also copying Joe Arvai and Nancy Beck in case they want to respond, either in writing or by phone, particularly as there is now no description of Administrator Pruitt's goals or activities in this area. While not necessary, we do have room in the abstract for additional language

Bernie

Bernard D. Goldstein, MD

Professor Emeritus and Dean Emeritus

University of Pittsburgh Graduate School of Public Health

130 Desoto St; Rm A-710

Pittsburgh PA 15261

Ex. 6 - Personal Privacy

From: White, Kimberly [mailto:Kimberly_White@americanchemistry.com]

Sent: Friday, May 19, 2017 6:22 PM

To: Goldstein, Bernard D <bdgold@pitt.edu>

Cc: Becker, Rick <Rick_Becker@americanchemistry.com>

Subject: RE: Follow-up on SRA Session

Dear Bernie:

Thanks for the additional information about the session and the abstract. We offer some suggestions to the abstract attached. The suggestions attempt to focus the abstract on the discussion regarding what are appropriate approaches for optimal provision of scientific advice to regulatory agencies and work to adjust some of the language that may be perceived as inflammatory.

Kind Regards,

Kimberly

Kimberly Wise White, Ph.D. | American Chemistry Council

Senior Director, Chemical Products & Technology Division

Kimberly_White@americanchemistry.com

700 2nd Street NE | Washington, DC | 20002

Ex. 6 - Personal Privacy

From: Goldstein, Bernard D [<mailto:bdgold@pitt.edu>]

Sent: Friday, May 19, 2017 2:53 PM

To: White, Kimberly

Cc: Becker, Rick

Subject: RE: Follow-up on SRA Session

Dear Dr White

Great news!!

My previous email to you is below; along with the original attachment of the preliminary draft

Bernie

Bernard D. Goldstein, MD

Emeritus Professor and Emeritus Dean

Graduate School of Public Health

University of Pittsburgh

Rm A710 Crabtree Hall

130 De Soto St

Pittsburgh, PA 15261

Ex. 6 - Personal Privacy

Dear Dr White

I am following up with you at the suggestion of Nancy Beck (email below) to request your involvement in a proposal for a Roundtable to be submitted to the Society for Risk Analysis for its annual meeting in Crystal City next December 10-13.

I've attached a short overview of Roundtables from the SRA web site along with a rough draft of the abstract. I am trying to focus the Roundtable on the parameters governing an effective science advisory process for a regulatory agency, rather than on the current controversy – although this is unlikely to be fully possible.

NOTE: no abstract would be needed from you, just an agreement to participate, give perhaps a 10 minute presentation and participate in the discussion during the 90 minute session. But your input on the proposal would be welcome.

One difference from the note below to Nancy is that I have been told that the proposal is more likely to be acceptable if it has a broader range of participants so it will probably 4-5 speakers rather than 3-4.

I had previously reached out to Richard Becker asking for whom to approach at ACC now that Nancy had left. His response was that ACC would be interested in participating but only if EPA did as well, which I fully understand. I know he is out of town today. As you no doubt know, ACC is on record supporting the EPA SAB Act that passed the House.

There are some time constraints in getting this completed, particularly as I will be at Dow Chemical for much of next week, so hope both that you can do this and that you can respond by midweek

Many thanks for your consideration

Bernie

Bernard D. Goldstein, MD

Emeritus Professor and Emeritus Dean

Graduate School of Public Health

University of Pittsburgh

Rm A710 Crabtree Hall

130 De Soto St

Pittsburgh, PA 15261

Ex. 6 - Personal Privacy

From: Goldstein, Bernard D
Sent: Thursday, May 18, 2017 2:28 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: Re: SRA panel

Happy to reframe. I originally had a quote from the congressman who sponsored it but this seemed too inflammatory for SRA. Will look at this again tonight and will contact Kimberly White

Sent from my iPhone

On May 18, 2017, at 12:08 PM, Beck, Nancy <Beck.Nancy@epa.gov> wrote:

Bernie,

I think the framing of the abstract is a bit biased and needs some work.

I cant and wont speak for ACC at all, but for this topic, I direct you to Kimberly White. She has testified in front of congress on these issues. Kimberly_White@americanchemistry.com.

If I have more time this week I will noodle the abstract but it's a bit of a busy time here.

Regards,
Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Ex. 6 - Personal Privacy

From: Goldstein, Bernard D [<mailto:bdgold@pitt.edu>]
Sent: Wednesday, May 17, 2017 12:41 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: SRA panel

Hi Nancy

Great to hear!!

Attached is what I've written so far, and some of the directions from the SRA web site. I'm about to run out for most of the rest of the afternoon. I'd like to get this out of the way as soon as reasonably possible as am at meetings at Dow most of next week.

No abstract would be needed from you so there is nothing written with your name on it that would have to go through the EPA process, at least as I understood it many, many years ago. (As the proposer, I would be the only one with my name on the proposed abstract, but would welcome your input and that of the other panelists on the proposal).

I'm envisioning the 3 or 4 panelists for the Roundtable would have about 15 min each for presentation and the rest of the 90 minutes would be for a facilitated discussion led by the moderator

I'm thinking of asking Granger Morgan or Terry Yosie to be the moderator, but your suggestion

for moderator or for another panelist who supports the ACC position on the SAB Act would be very much appreciated.

Best regards

Bernie

Bernard D. Goldstein, MD

Emeritus Professor and Emeritus Dean

Graduate School of Public Health

University of Pittsburgh

Rm A710 Crabtree Hall

130 De Soto St

Pittsburgh, PA 15261

Ex. 6 - Personal Privacy

From: Beck, Nancy [<mailto:Beck.Nancy@epa.gov>]

Sent: Wednesday, May 17, 2017 12:22 PM

To: Goldstein, Bernard D <bdgold@pitt.edu>

Subject: SRA panel

Hi Bernie,

Got your message and am happy to consider the request. Can you send me all the information on the proposal (abstract, goals, participants, etc)?

I will have to find out if I have to run this through a clearance process—not sure how that works yet and if those procedures apply to me.

Thanks,
Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator

Office of Chemical Safety and Pollution Prevention

Ex. 6 - Personal Privacy

From: White, Kimberly [mailto:Kimberly_White@americanchemistry.com]
Sent: Friday, May 19, 2017 2:35 PM
To: Goldstein, Bernard D <bdgold@pitt.edu>
Cc: Becker, Rick <Rick_Becker@americanchemistry.com>
Subject: Follow-up on SRA Session

Dear Dr. Goldstein:

Thank you for your voicemail earlier today. I have had an opportunity to follow-up with Rick (cc'd on this email) and I understand you have a commitment from EPA to participate. Given the confirmation of EPA's participation, we will also confirm ACC's participation. Could you send me the proposed abstract or session description? Also it would be helpful to know of any additional information you need from ACC for the session and any deadlines.

Kind Regards,

Kimberly Wise White, Ph.D. | American Chemistry Council

Senior Director, Chemical Products & Technology Division

Kimberly_White@americanchemistry.com

700 2nd Street NE | Washington, DC | 20002

Ex. 6 - Personal Privacy

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www.americanchemistry.com

To: Akihiko Hirose[akihikoh@dranihs.net];
 rhryuichihasegawa08@gmail.com[rhryuichihasegawa08@gmail.com]; 'Michael L. Caldwell'[MCaldwell@zacfirm.com]; Beck, Nancy[Beck.Nancy@epa.gov]; Birchfield, Norman[Birchfield.Norman@epa.gov]; yamazaki[k-yamazaki@jisha.or.jp]; kmdilwali@intsci.com[kmdilwali@intsci.com]; 'Michael L. Caldwell'[MCaldwell@zacfirm.com]; Pierre_Therriault@hc-sc.gc.ca[Pierre_Therriault@hc-sc.gc.ca]; Richard Charron[Richard.Charron@hc-sc.gc.ca]; Sams, Reeder[Sams.Reeder@epa.gov];
 mhoneycu@tceq.state.tx.us[mhoneycu@tceq.state.tx.us]; Deshpande, Satish (MOECC)[Satish.Deshpande@ontario.ca]; sarah.labib@canada.ca[sarah.labib@canada.ca]; Shannon Ethridge[sethridg@tceq.state.tx.us]; Barbara Sassi[barbara.sassi@health.mo.gov]; dennis.wambuguh@health.mo.gov[dennis.wambuguh@health.mo.gov]; Chris Prucha[cprucha@wm.com]; h-kano@jisha.or.jp[h-kano@jisha.or.jp]; Maier, Michael (maierma)[maierma@ucmail.uc.edu]; t-kasai@jisha.or.jp[t-kasai@jisha.or.jp]; sethridg@tceq.state.tx.us[sethridg@tceq.state.tx.us]; Robert Maronpot[maronpot@me.com]; Whalan, John[Whalan.John@epa.gov]; James E. Klaunig[jklauni@indiana.edu]; Jayne Wright[jayne@jaynewright.co.uk]; Nadine Weinberg[nadine.weinberg@erm.com]; Garoutte, Jonathan[Jonathan.Garoutte@health.mo.gov]; flagac@michigan.gov[flagac@michigan.gov]; Joseph.Haney@tceq.texas.gov[Joseph.Haney@tceq.texas.gov]; Phelka, Amanda[aphelka@nsf.org]; jenglish@nsf.org[jenglish@nsf.org]; Laessig, Susan[Laessig.Susan@epa.gov]; Herbert, Ron (NIH/NIEHS) [E][herbert@niehs.nih.gov]; oono-yurie@mhlw.go.jp[oono-yurie@mhlw.go.jp]; toxpathmcc[toxpathmcc@bellsouth.net]; Jeff.Wenzel@health.mo.gov[Jeff.Wenzel@health.mo.gov]; Maria Hegstad[mhegstad@iwpnews.com]; Doug Wolf[Wolf.Doug@epamail.epa.gov]; helen.goeden@state.mn.us[helen.goeden@state.mn.us]; James.kelly@state.mn.us[James.kelly@state.mn.us]; Franz, Christina[Christina_Franz@americanchemistry.com]; Kylie Brockenfelt[KBrockenfelt@epl-inc.com]; rieds@michigan.gov[rieds@michigan.gov]; 'Sager, Shawn'[Shawn.Sager@arcadis.com]; HOWARD, WILLIAM B GS-13 USAF AFMC AFCEC/CZTE[william.howard.40@us.af.mil]; Hamlin, Mel (NIH/NIEHS) [C] (hamlin@niehs.nih.gov)[hamlin@niehs.nih.gov]; ruckner@rx.uga.edu[ruckner@rx.uga.edu]; Harvey Clewell[HClewell@thehamner.org]; david_dorman@ncsu.edu[david_dorman@ncsu.edu]; fjmillar@nc.rr.com[fjmillar@nc.rr.com]; rpsharma@uga.edu[rpsharma@uga.edu]; Vandenberg, John[Vandenberg.John@epa.gov]
Cc: Jeri.Higginbotham@ky.gov[Jeri.Higginbotham@ky.gov]; jcrum@hampmathews.com[jcrum@hampmathews.com]; burleighflayer@ppg.com[burleighflayer@ppg.com]; Nance, Patricia (nancepm)[nancepm@ucmail.uc.edu]; 'Forsberg, Norman'[Norman.Forsberg@arcadis.com]; 'Mark Lafronconi'[Mark.Lafronconi@erm.com]; Reichard, John (reichajf)[reichajf@ucmail.uc.edu]
From: Dourson, Michael (doursoml)
Sent: Mon 6/5/2017 10:08:41 PM
Subject: In Print---1,4-Dioxane Publication

Dear Colleagues

On behalf of the authors, I am pleased to let you know that our publication is now in print as shown below. The paper was developed under the umbrella of the Alliance for Risk Assessment (ARA), and is open access thanks to Norm Forsberg and his company Arcadis. Please feel free to share this paper as needed.

Cheers!

Michael Dourson

— Risk Science Center (formerly TERA Center) sponsors the International Toxicity Estimates for Risk (ITER) database of risk assessment values on Toxnet: <http://toxnet.nlm.nih.gov/>



From: RSS Feed via IFTTT <weeklydigest@ifttt.com>

Date: Monday, June 5, 2017 at 8:14 AM

To: Michael Dourson <doursoml@ucmail.uc.edu>

Subject: Weekly Digest: If new feed item

from <http://rss.sciencedirect.com/publication/science/02732300>, then add to weekly digest sent to michael.dourson@uc.edu on (7 items)

Update: Mode of action (MOA) for liver tumors induced by oral exposure to 1,4-dioxane

Publication date: August 2017

Source: Regulatory Toxicology and Pharmacology, Volume 88

Author(s): Michael L. Dourson, Jeri Higginbotham, Jeff Crum, Heather Burleigh-Flayer, Patricia Nance, Norman D. Forsberg, Mark Lafranconi, John Reichard

Previous work has shown that the weight of evidence supports the hypothesis that 1,4-dioxane causes liver tumors in rodents through cytotoxicity and subsequent regenerative hyperplasia. Questions regarding a lack of concordant findings for this mode of action (MOA) in mice have not been resolved, however. In the current work, a reanalysis of data from two chronic mouse cancer bioassays on 1,4-dioxane, one 13-week mouse study, seven rat cancer bioassays, coupled with other data such as 1,4-dioxane's negative mutagenicity, its lack of up-regulated DNA repair, and the appearance of liver tumors with a high background incidence, support the conclusion that rodent liver tumors, including those in mice, are evoked by a regenerative hyperplasia MOA. The initiating event for this MOA is metabolic saturation of 1,4-dioxane. Above metabolic saturation, higher doses of the parent compound cause an ever increasing toxicity in the rodent liver as evidenced by higher blood levels of enzymes indicative of liver cell damage and associated histopathology that occurs in a dose and time related manner. Importantly, alternative modes of action can be excluded. The observed liver toxicity has a threshold in the dose scale at or below levels that saturate metabolism, and generally in the range of 9.6–42 mg/kg-day for rats and 57 to 66 mg/kg-day for mice. It follows that threshold approaches to the assessment of this chemical's toxicity are

supported by the non-mutagenic, metabolic saturation kinetics, and cytotoxicity-generated regenerative repair information available for 1,4-dioxane promoted rodent liver tumors.

via ScienceDirect Publication: Regulatory Toxicology and Pharmacology <http://ift.tt/2r6ix2E> May 30, 2017 at 02:02AM

via RSS

Feed <http://rss.sciencedirect.com/action/redirectFile?&zone=main&Activity=feed&usageTy>

From: Michael Dourson <doursoml@ucmail.uc.edu>

Date: Thursday, February 23, 2017 at 2:28 PM

To: Akihiko Hirose <akihikoh@dranihs.net>, "rhryuichihasegawa08@gmail.com" <rhryuichihasegawa08@gmail.com>, "Michael L. Caldwell" <MCaldwell@zacfirm.com>, "Beck, Nancy" <Nancy_Beck@americanchemistry.com>, "Birchfield, Norman" <Birchfield.Norman@epa.gov>, yamazaki <k-yamazaki@jisha.or.jp>, "kmdilwali@intsci.com" <kmdilwali@intsci.com>, "Michael L. Caldwell" <MCaldwell@zacfirm.com>, "Pierre Therriault@hc-sc.gc.ca" <Pierre.Therriault@hc-sc.gc.ca>, Richard Charron <Richard.Charron@hc-sc.gc.ca>, "Sams, Reeder" <Sams.Reeder@epa.gov>, Michael Honeycutt <MHoneycu@tceq.state.tx.us>, "Deshpande, Satish (MOECC)" <Satish.Deshpande@ontario.ca>, "Labib, Sarah (HC/SC)" <sarah.labib@canada.ca>, Shannon Ethridge <sethridg@tceq.state.tx.us>, Barbara Sassi <barbara.sassi@health.mo.gov>, Dennis Wambuguh <dennis.wambuguh@health.mo.gov>, Chris Prucha <cprucha@wm.com>, "h-kano@jisha.or.jp" <h-kano@jisha.or.jp>, Andy Maier <maierma@ucmail.uc.edu>, "t-kasai@jisha.or.jp" <t-kasai@jisha.or.jp>, "sethridg@tceq.state.tx.us" <sethridg@tceq.state.tx.us>, Robert Maronpot <maronpot@me.com>, "Whalan, John" <Whalan.John@epa.gov>, "Klaunig, James E." <jklauni@indiana.edu>, Jayne Wright <jayne@jaynewright.co.uk>, Nadine Weinberg <nadine.weinberg@erm.com>, "Garoutte, Jonathan" <Jonathan.Garoutte@health.mo.gov>, "Flaga, Christine (DEQ)" <FLAGAC@michigan.gov>, "Joseph.Haney@tceq.texas.gov" <Joseph.Haney@tceq.texas.gov>, "Phelka, Amanda" <aphelka@nsf.org>, "English, Joanne Caroline" <jenglish@nsf.org>, "Laessig, Susan" <Laessig.Susan@epa.gov>, "Herbert, Ron (NIH/NIEHS) [E]" <herbert@niehs.nih.gov>, "oono-yurie@mhlw.go.jp" <oono-yurie@mhlw.go.jp>, toxpathmcc <toxpathmcc@bellsouth.net>, "Jeff.Wenzel@health.mo.gov" <Jeff.Wenzel@health.mo.gov>, Maria Hegstad <mhegstad@iwpnews.com>, Doug Wolf <Wolf.Doug@epamail.epa.gov>, "Goeden, Helen (MDH)" <Helen.Goeden@state.mn.us>, "Kelly, James (MDH)" <james.kelly@state.mn.us>, "Franz, Christina" <Christina_Franz@americanchemistry.com>, Kylie Brockenfelt <KBrockenfelt@epl-inc.com>, "Ries, Divinia (DEQ)" <RIESD@michigan.gov>, "Sager, Shawn" <Shawn.Sager@arcadis.com>, "HOWARD, WILLIAM B GS-13 USAF AFMC AFCEC/CZTE" <william.howard.40@us.af.mil>, "Hamlin, Mel (NIH/NIEHS) [C]" <hamlin@niehs.nih.gov> <hamlin@niehs.nih.gov>, "ruckner@rx.uga.edu" <ruckner@rx.uga.edu>, Harvey Clewell <HClewell@thehamner.org>, "david_dorman@ncsu.edu" <david_dorman@ncsu.edu>, "fjmiller@nc.rr.com" <fjmiller@nc.rr.com>, "rpsharma@uga.edu" <rpsharma@uga.edu>, John Vandenberg <Vandenberg.John@epamail.epa.gov>
Cc: "Higginbotham, Jeri" (EEC) <Jeri.Higginbotham@ky.gov>, "jcrum@hampmathews.com" <jcrum@hampmathews.com>, "Burleigh-Flayer, Heather" <burleighflayer@ppg.com>, Patricia Nance

<nancepm@ucmail.uc.edu>, "'Forsberg, Norman'" <Norman.Forsberg@arcadis.com>, 'Mark Lafranconi'
<Mark.Lafranconi@erm.com>

Subject: Accepted 1,4-Dioxane Publication

Dear Colleagues

On behalf of the authors listed in the CC section of this email, it gives me great pleasure to state that a manuscript entitled "Update: Mode of Action (MOA) for Liver Tumors Induced by Oral Exposure to 1,4-Dioxane" has been accepted by Regulatory Toxicology and Pharmacology. An abstract is found below.

This work was conducted under the auspices of the Alliance for Risk Assessment (ARA), and involved multiple groups acting collaboratively. Updates of this accepted text prior to it being published will be posted on the Alliance for Risk Assessment (ARA) website, specifically, <http://allianceforrisk.org/14-dioxane-analysis>.

Please feel free to let your colleagues know as well.

Sincerely,



Michael L. Dourson, Ph.D., DABT, FATS, FSRA
Professor
Risk Science Center (formerly TERA)
Department of Environmental Health
University of Cincinnati, College of Medicine
160 Panzeca Way
Cincinnati OH 45267-0056

Ex. 6 - Personal Privacy



Abstract

Previous scientific studies show that the weight of evidence supports the hypothesis that 1,4-dioxane causes liver tumors in rodents through cytotoxicity and subsequent regenerative

hyperplasia. Questions regarding a lack of concordant findings for this mode of action (MOA) in mice have not been resolved, however. In the current work, a reanalysis of data from two chronic mouse cancer bioassays on 1,4-dioxane, one 13-week mouse study, seven rat cancer bioassays, coupled with other data demonstrating negative mutagenicity, lack of up-regulated DNA repair, and the appearance of liver tumors with a high background incidence, support the conclusion that rodent liver tumors, including those in mice, are evoked by a regenerative hyperplasia MOA. The initiating event for this MOA is metabolic saturation of 1,4-dioxane. Above metabolic saturation, higher doses of the parent compound cause an ever increasing toxicity in the rodent liver as evidenced by higher blood levels of enzymes indicative of liver cell damage and associated histopathology that occurs in a dose and time related manner. Importantly, alternative modes of action can be excluded. The observed liver toxicity has a threshold in the dose scale at or below levels that saturate metabolism, and generally in the range of 9.6 to 42 mg/kg-day for rats and 57 to 66 mg/kg-day for mice. It follows that threshold approaches to the assessment of this chemical's toxicity are supported by the non-mutagenic, metabolic saturation kinetics, and cytotoxicity-generated regenerative repair information available for 1,4-dioxane promoted rodent liver tumors.

From: eesserver@eesmail.elsevier.com [<mailto:eesserver@eesmail.elsevier.com>]

Sent: Thursday, February 23, 2017 10:33 AM

To: Nance, Patricia (nancepm) <nancepm@ucmail.uc.edu>; pnance1972@gmail.com

Subject: RTP-16-335R2: Final Decision

Ms. No.: RTP-16-335R2

Title: Update: Mode of Action (MOA) for Liver Tumors Induced by Oral Exposure to 1,4-Dioxane

Corresponding Author: Ms. Patricia Nance

Authors: Michael Dourson; Jeri Higginbotham; Jeff Crum; Heather Burleigh-Flayer; Norman Forsberg; Mark Lafranconi

Dear Ms. Nance,

Congratulations. I am pleased to inform you that your manuscript, referenced above, has been accepted for publication in Regulatory Toxicology and Pharmacology.

Many thanks for this paper. We look forward to the submission of your future manuscripts to Regulatory Toxicology and Pharmacology.

Your accepted manuscript will now be transferred to our production department and work will begin on creation of the proof. If we need any additional information to create the proof, we will let you know. If not, you will be contacted again in the next few days with a request to approve the proof and to complete a number of online forms that are required for publication.

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With kind regards,

Dr. Gio Batta Gori, Editor-in-Chief
Regulatory Toxicology and Pharmacology
E-mail: rtp@elsevier.com

To: Beck, Nancy[Beck.Nancy@epa.gov]
From: Goldstein, Bernard D
Sent: Tue 5/23/2017 12:05:58 AM
Subject: RE: Follow-up on SRA Session

Understood. Will send you the likely final abstract if I don't hear about any other changes

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
Sent: Monday, May 22, 2017 6:49 PM
To: Goldstein, Bernard D <bdgold@pitt.edu>
Subject: RE: Follow-up on SRA Session

Got it. When you have a final abstract send it my way and I'll take a look.

It is a bit awkward.. I think I can be on a panel with them, but do not want to be collaborating with them, or even seen as collaborating with them.

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Ex. 6 - Personal Privacy

From: Goldstein, Bernard D [mailto:bdgold@pitt.edu]
Sent: Monday, May 22, 2017 3:52 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: Follow-up on SRA Session

Sorry to be unclear. I do need names for the submission, but do not need your participation in the preparation of the abstract. I apologize, as I should have realized that this might be a problem for you

Needless to say, you could withdraw at any time.

Bernie

From: Beck, Nancy [<mailto:Beck.Nancy@epa.gov>]
Sent: Monday, May 22, 2017 7:42 AM
To: Goldstein, Bernard D <bdgold@pitt.edu>
Subject: RE: Follow-up on SRA Session

Bernie,

As I am recused from interactions with ACC, it's a bit awkward for me to be planning a session with them.

As you said you don't need names just yet for the submission, why don't you just move ahead without me and let's circle back in the fall to see if it makes sense for me to join the panel.

Regards,

Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Ex. 6 - Personal Privacy

beck.nancy@epa.gov

From: Goldstein, Bernard D [<mailto:bdgold@pitt.edu>]
Sent: Monday, May 22, 2017 5:24 AM
To: White, Kimberly <Kimberly_White@americanchemistry.com>
Cc: Rick Becker<Rick_Becker@americanchemistry.com>; Joe Arvai <jarvai@umich.edu>; Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: Follow-up on SRA Session

Hi Kimberly

Your changes are OK with me, but I have added a few words (“and decreasing the likelihood of the involvement of knowledgeable academic scientists in EPA review processes”) to reflect the substantial concern of the academic community about the following provision in the SAB Act. (I also think that the provision is short-sighted from an industry perspective).

“(H) a Board member shall have no current grants or contracts from the Environmental Protection Agency

and shall not apply for a grant or contract for 3 years following the end of that member’s service on the Board.”

There is also other language in the Act which could be interpreted as the above provision being applicable to not only full SAB Board membership, but to the members of any EPA review process of any hazard or risk assessment

Let me know if the new language is acceptable to you. I’m also copying Joe Arvai and Nancy Beck in case they want to respond, either in writing or

by phone, particularly as there is now no description of Administrator Pruitt's goals or activities in this area. While not necessary, we do have room in the abstract for additional language

Bernie

Bernard D. Goldstein, MD

Professor Emeritus and Dean Emeritus

University of Pittsburgh Graduate School of Public Health

130 Desoto St; Rm A-710

Pittsburgh PA 15261

Ex. 6 - Personal Privacy

From: White, Kimberly [mailto:Kimberly_White@americanchemistry.com]

Sent: Friday, May 19, 2017 6:22 PM

To: Goldstein, Bernard D <bdgold@pitt.edu>

Cc: Becker, Rick <Rick_Becker@americanchemistry.com>

Subject: RE: Follow-up on SRA Session

Dear Bernie:

Thanks for the additional information about the session and the abstract. We offer some suggestions to the abstract attached. The suggestions attempt to focus the abstract on the discussion regarding what are appropriate approaches for optimal provision of scientific advice to regulatory agencies and work to adjust some of the language that may be perceived as inflammatory.

Kind Regards,

Kimberly

Kimberly Wise White, Ph.D. | American Chemistry Council

Senior Director, Chemical Products & Technology Division

Kimberly_White@americanchemistry.com

700 2nd Street NE | Washington, DC | 20002

Ex. 6 - Personal Privacy

From: Goldstein, Bernard D [<mailto:bdgold@pitt.edu>]

Sent: Friday, May 19, 2017 2:53 PM

To: White, Kimberly

Cc: Becker, Rick

Subject: RE: Follow-up on SRA Session

Dear Dr White

Great news!!

My previous email to you is below; along with the original attachment of the preliminary draft

Bernie

Bernard D. Goldstein, MD
Emeritus Professor and Emeritus Dean
Graduate School of Public Health
University of Pittsburgh
Rm A710 Crabtree Hall
130 De Soto St
Pittsburgh, PA 15261

Ex. 6 - Personal Privacy

Dear Dr White

I am following up with you at the suggestion of Nancy Beck (email below) to request your involvement in a proposal for a Roundtable to be submitted to the Society for Risk Analysis for its annual meeting in Crystal City next December 10-13.

I've attached a short overview of Roundtables from the SRA web site along with a rough draft of the abstract. I am trying to focus the Roundtable on the parameters governing an effective science advisory process for a regulatory agency, rather than on the current controversy – although this is unlikely to be fully possible.

NOTE: no abstract would be needed from you, just an agreement to participate, give perhaps a 10 minute presentation and participate in the discussion during the 90 minute session. But your input on the proposal would be welcome.

One difference from the note below to Nancy is that I have been told that the proposal is more likely to be acceptable if it has a broader range of participants so it will probably 4-5 speakers rather than 3-4.

I had previously reached out to Richard Becker asking for whom to approach at ACC now that Nancy had left. His response was that ACC would be interested in participating but only if EPA did as well, which I fully understand. I know he is out of town today. As you no doubt know, ACC is on record supporting the EPA SAB Act that passed the House.

There are some time constraints in getting this completed, particularly as I will be at Dow Chemical for much of next week, so hope both that you can do this and that you can respond by midweek

Many thanks for your consideration

Bernie

Bernard D. Goldstein, MD

Emeritus Professor and Emeritus Dean

Graduate School of Public Health

University of Pittsburgh

Rm A710 Crabtree Hall

130 De Soto St

Pittsburgh, PA 15261

Ex. 6 - Personal Privacy

From: Goldstein, Bernard D
Sent: Thursday, May 18, 2017 2:28 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: Re: SRA panel

Happy to reframe. I originally had a quote from the congressman who sponsored it but this seemed too inflammatory for SRA. Will look at this again tonight and will contact Kimberly White

Sent from my iPhone

On May 18, 2017, at 12:08 PM, Beck, Nancy <Beck.Nancy@epa.gov> wrote:

Bernie,

I think the framing of the abstract is a bit biased and needs some work.

I cant and wont speak for ACC at all, but for this topic, I direct you to Kimberly White. She has testified in front of congress on these issues. Kimberly_White@americanchemistry.com.

If I have more time this week I will noodle the abstract but it's a bit of a busy time here.

Regards,
Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Ex. 6 - Personal Privacy

Ex. 6 - Personal Privacy

From: Goldstein, Bernard D [<mailto:bdgold@pitt.edu>]
Sent: Wednesday, May 17, 2017 12:41 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: SRA panel

Hi Nancy

Great to hear!!

Attached is what I've written so far, and some of the directions from the SRA web site. I'm about to run out for most of the rest of the afternoon. I'd like to get this out of the way as soon as reasonably possible as am at meetings at Dow most of next week.

No abstract would be needed from you so there is nothing written with your name on it that would have to go through the EPA process, at least as I understood it many, many years ago. (As the proposer, I would be the only one with my name on the proposed abstract, but would welcome your input and that of the other panelists on the proposal).

I'm envisioning the 3 or 4 panelists for the Roundtable would have about 15 min each for presentation and the rest of the 90 minutes would be for a facilitated discussion led by the moderator

I'm thinking of asking Granger Morgan or Terry Yosie to be the moderator, but your suggestion for moderator or for another panelist who supports the ACC position on the SAB Act would be very much appreciated.

Best regards

Bernie

Bernard D. Goldstein, MD

Emeritus Professor and Emeritus Dean

Graduate School of Public Health

University of Pittsburgh

Rm A710 Crabtree Hall

130 De Soto St

Pittsburgh, PA 15261

Ex. 6 - Personal Privacy

From: Beck, Nancy [<mailto:Beck.Nancy@epa.gov>]

Sent: Wednesday, May 17, 2017 12:22 PM

To: Goldstein, Bernard D <bdgold@pitt.edu>

Subject: SRA panel

Hi Bernie,

Got your message and am happy to consider the request. Can you send me all the information on the proposal (abstract, goals, participants, etc)?

I will have to find out if I have to run this through a clearance process—not sure how that works yet and if those procedures apply to me.

Thanks,
Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator

Office of Chemical Safety and Pollution Prevention

Ex. 6 - Personal Privacy

beck.nancy@epa.gov

From: White, Kimberly [mailto:Kimberly_White@americanchemistry.com]

Sent: Friday, May 19, 2017 2:35 PM

To: Goldstein, Bernard D <bdgold@pitt.edu>

Cc: Becker, Rick <Rick_Becker@americanchemistry.com>

Subject: Follow-up on SRA Session

Dear Dr. Goldstein:

Thank you for your voicemail earlier today. I have had an opportunity to follow-up with Rick (cc'd on this email) and I understand you have a commitment from EPA to participate. Given the confirmation of EPA's

participation, we will also confirm ACC's participation. Could you send me the proposed abstract or session description? Also it would be helpful to know of any additional information you need from ACC for the session and any deadlines.

Kind Regards,

Kimberly Wise White, Ph.D. | American Chemistry Council

Senior Director, Chemical Products & Technology Division

Kimberly_White@americanchemistry.com

700 2nd Street NE | Washington, DC | 20002

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To: Goldstein, Bernard D[bdgold@pitt.edu]
Cc: Rick_Becker@americanchemistry.com[Rick_Becker@americanchemistry.com]; Joe Arvai[jlarvai@umich.edu]; Beck, Nancy[Beck.Nancy@epa.gov]
From: White, Kimberly
Sent: Mon 5/22/2017 11:32:02 AM
Subject: RE: Follow-up on SRA Session

Dear Bernie:

I'm okay with your changes. Thanks

Kind Regards,

Kimberly Wise White, Ph.D. | American Chemistry Council

Senior Director, Chemical Products & Technology Division

Kimberly.White@americanchemistry.com

700 2nd Street NE | Washington, DC | 20002

Ex. 6 - Personal Privacy

From: Goldstein, Bernard D [mailto:bdgold@pitt.edu]
Sent: Monday, May 22, 2017 5:24 AM
To: White, Kimberly
Cc: Becker, Rick; Joe Arvai; Beck, Nancy
Subject: RE: Follow-up on SRA Session

Hi Kimberly

Your changes are OK with me, but I have added a few words (“and decreasing the likelihood of the involvement of knowledgeable academic scientists in EPA review processes”) to reflect the substantial concern of the academic

community about the following provision in the SAB Act. (I also think that the provision is short-sighted from an industry perspective).

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Let me know if the new language is acceptable to you. I’m also copying Joe Arvai and Nancy Beck in case they want to respond, either in writing or by phone, particularly as there is now no description of Administrator Pruitt’s goals or activities in this area. While not necessary, we do have room in the abstract for additional language

Bernie

Bernard D. Goldstein, MD

Professor Emeritus and Dean Emeritus

University of Pittsburgh Graduate School of Public Health

130 Desoto St; Rm A-710

Pittsburgh PA 15261

Ex. 6 - Personal Privacy

Ex. 6 - Personal Privacy

From: White, Kimberly [mailto:Kimberly_White@americanchemistry.com]
Sent: Friday, May 19, 2017 6:22 PM
To: Goldstein, Bernard D <bdgold@pitt.edu>
Cc: Becker, Rick <Rick_Becker@americanchemistry.com>
Subject: RE: Follow-up on SRA Session

Dear Bernie:

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Kind Regards,

Kimberly

Kimberly Wise White, Ph.D. | American Chemistry Council

Senior Director, Chemical Products & Technology Division

Kimberly_White@americanchemistry.com

700 2nd Street NE | Washington, DC | 20002

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From: Goldstein, Bernard D [<mailto:bdgold@pitt.edu>]
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To: White, Kimberly
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Dear Dr White

Great news!!

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Bernie

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Emeritus Professor and Emeritus Dean

Graduate School of Public Health

University of Pittsburgh

Rm A710 Crabtree Hall

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Deputy Assistant Administrator, OCSPP

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Cc: Rick_Becker@americanchemistry.com[Rick_Becker@americanchemistry.com]; Joe Arvai[jlarvai@umich.edu]; Beck, Nancy[Beck.Nancy@epa.gov]
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Sent: Mon 5/22/2017 9:23:56 AM
Subject: RE: Follow-up on SRA Session
[SRA ROUNDTABLE+Suggested Edits plus BDG.docx](#)

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To: Beck, Nancy[Beck.Nancy@epa.gov]
From: Rutigliano, Marian
Sent: Tue 5/16/2017 2:20:14 PM
Subject: RE: Rutigliano - met at SOT

Nancy,

Well, it's a nice surprise to follow up and here you are at the Agency. Congratulations!

It would be great to talk when you have a chance after settling in at OCSPP. I work in Potomac Yard and live in Northern Baltimore County, so can stop by in the afternoons (from 3:30 on) before heading home. Let me know the best days of week for you.

Sincerely,

Marian

Marian Rutigliano, DO, MSEV
Environmental Health Scientist
USEPA/ORD/NCEA
Mail Code: 8601P
1200 Pennsylvania Ave, NW
Washington, DC 20460
rutigliano.marian@epa.gov

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From: Beck, Nancy [mailto:Nancy_Beck@americanchemistry.com]
Sent: Monday, April 17, 2017 9:19 AM
To: Rutigliano, Marian <Rutigliano.Marian@epa.gov>
Subject: RE: Rutigliano - met at SOT

Hi Marian,

Thank you for following up! TEF is most definitely interested in hearing from more voices to help us educate the public.

We have a board meeting in early May and it would make the most sense if we chat after that. Apologies for the delay.

Regards,
Nancy

From: Rutigliano, Marian [mailto:Rutigliano.Marian@epa.gov]
Sent: Friday, April 14, 2017 12:55 PM
To: Beck, Nancy <Nancy_Beck@americanchemistry.com>
Subject: Rutigliano - met at SOT

Dear Dr. Beck,

We met at SOT in Baltimore last month, when you gave a talk on communicating science to the public. We got to chat briefly and it seemed good to set up a time to talk more about this and the work at ACC. I am currently assigned in the IRIS program at EPA but have a unique and extensive background as a physician and environmental engineer.

I enjoyed your talk at SOT and look forward to continuing the discussion. When are the best

times of day/days of week to set up a time to talk for 30-60 minutes?

Kind regards,

Marian Rutigliano

Marian Rutigliano, DO, MSEV

Environmental Health Scientist

USEPA/ORD/NCEA

Mail Code: 8601P

1200 Pennsylvania Ave, NW

Washington, DC 20460

rutigliano.marian@epa.gov

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To: Beck, Nancy[Beck.Nancy@epa.gov]
From: Dourson, Michael (doursoml)
Sent: Fri 5/12/2017 4:33:17 PM
Subject: FW: Offered symposium
[21stDRA 2018 SOT Symposium.docx](#)

Nancy

Sorry to miss your email the first time...

Cheers!

Michael...

...L. Dourson, Ph.D., DABT, FATS, FSRA
Professor
Risk Science Center (formerly TERA)
Department of Environmental Health
University of Cincinnati, College of Medicine
160 Panzeca Way
Cincinnati OH 45267-0056

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From: Michael Dourson <doursoml@ucmail.uc.edu>
Date: Friday, May 12, 2017 at 12:26 PM
To: Edward Calabrese <edwardc@schoolph.umass.edu>, "nancy.beck@epa.gov" <nancy.beck@epa.gov>, Daniel Krewski <dkrewski@uottawa.ca>, "Manibusan, Mary" <mmanibusan@exponent.com>, "Becker, Rick" <Rick_Becker@americanchemistry.com>, KASS Georges <Georges.KASS@efsa.europa.eu>
Cc: "Fitzpatrick, Suzanne" <Suzanne.Fitzpatrick@fda.hhs.gov>
Subject: FW: Offered symposium

Dear Colleagues

Please find attached a developing draft of a to-be-submitted symposium for next year's Society of Toxicology annual meeting. Your thoughts on individual abstracts and overall descriptions are most welcome. We will be formally submitting this next week early, so comments by this Sunday evening are needed.

Cheers!

Michael

— Risk Science Center (formerly TERA Center) sponsors the International Toxicity Estimates for Risk (ITER) database of risk assessment values on Toxnet: <http://toxnet.nlm.nih.gov/>



From: Michael Dourson <doursoml@ucmail.uc.edu>

Date: Friday, May 12, 2017 at 12:21 PM

To: Elizabeth Vancza <elizabeth.vancza@safebridge.com>

Cc: "Fitzpatrick, Suzanne" <Suzanne.Fitzpatrick@fda.hhs.gov>, "Ohanian, Edward" <Ohanian.Edward@epa.gov>, "marie.c.fortin@gmail.com" <marie.c.fortin@gmail.com>

Subject: Offered symposium

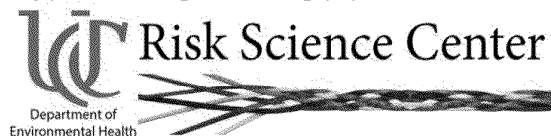
Dear Liz

I so much apologize for this late breaking symposium. Needless to say, we would highly value your committee's thoughts on this prior to the deadline of next Monday (or so). We completely understand if your group is not able to turn this around.

Cheers!

Michael

-- *If you can't explain it simply, you don't understand it well enough. Albert Einstein*



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Subject: Re: Offered symposium

[image001.jpg](#)

[image002.jpg](#)

[image003.jpg](#)

Nancy

Thanks. I will ask some one other of your authors.

Cheers!

Michael

—The right to search for the truth implies also a duty; one must not conceal any part of what one has recognized to be true. Albert Einstein.



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Date: Friday, May 12, 2017 at 2:05 PM
To: Michael Dourson <doursoml@ucmail.uc.edu>
Subject: RE: Offered symposium

Mike,

I need to be very careful about blurring lines between ACC and EPA. Not to mention clearance processes. Based on my learnings it would be highly unlikely that I would ever get clearance to do a presentation on work that I conducted at ACC. Even more sensitivity if its during the first year. Thus I will have to back out of this.

Bill Farland, Lynn Pottenger, or Jeff Lewis could do this well (and yourself as well....).

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Subject: FW: Offered symposium

Nancy

Sorry to miss your email the first time...

Cheers!

Michael...

...L. Dourson, Ph.D., DABT, FATS, FSRA

Professor

Risk Science Center (formerly TERA)

Department of Environmental Health
University of Cincinnati, College of Medicine
160 Panzeca Way
Cincinnati OH 45267-0056

Ex. 6 - Personal Privacy

<http://eh.uc.edu/tera/>



From: Michael Dourson <doursoml@ucmail.uc.edu>
Date: Friday, May 12, 2017 at 12:26 PM
To: Edward Calabrese <edwardc@schoolph.umass.edu>, "nancy.beck@epa.gov" <nancy.beck@epa.gov>, Daniel Krewski <dkrewski@uottawa.ca>, "Manibusan, Mary" <mmanibusan@exponent.com>, "Becker, Rick" <Rick_Becker@americanchemistry.com>, KASS Georges <Georges.KASS@efsa.europa.eu>
Cc: "Fitzpatrick, Suzanne" <Suzanne.Fitzpatrick@fda.hhs.gov>
Subject: FW: Offered symposium

Dear Colleagues

Please find attached a developing draft of a to-be-submitted symposium for next year's Society of Toxicology annual meeting. Your thoughts on individual abstracts and overall descriptions are most welcome. We will be formally submitting this next week early, so comments by this Sunday evening are needed.

Cheers!

Michael

— Risk Science Center (formerly TERA Center) sponsors the International Toxicity Estimates for Risk (ITER) database of risk assessment values on Toxnet: <http://toxnet.nlm.nih.gov/>



From: Michael Dourson <doursoml@ucmail.uc.edu>
Date: Friday, May 12, 2017 at 12:21 PM
To: Elizabeth Vancza <elizabeth.vancza@safebridge.com>
Cc: "Fitzpatrick, Suzanne" <Suzanne.Fitzpatrick@fda.hhs.gov>, "Ohanian, Edward" <Ohanian.Edward@epa.gov>, "marie.c.fortin@gmail.com" <marie.c.fortin@gmail.com>
Subject: Offered symposium

Dear Liz

I so much apologize for this late breaking symposium. Needless to say, we would highly value your committee's thoughts on this prior to the deadline of next Monday (or so). We completely understand if your group is not able to turn this around.

Cheers!

Michael

-- If you can't explain it simply, you don't understand it well enough. Albert Einstein



To: Beck, Nancy[Beck.Nancy@epa.gov]
Cc: Katya Tsaïoun[ktsaiou1@jhu.edu]
From: Sebastian Hoffmann
Sent: Wed 5/10/2017 12:23:16 PM
Subject: Primer: update

Hi Nancy,

First, congratulations to your new jobs!
Not being familiar with EPA, but it sounds like a very interesting challenge!

The time granted by the journal for reviewing the proofs is two days only. The journal expects our reply latest by tomorrow.
Would it be possible to get EPA approval until tomorrow?

If not, I would like to suggest that we add your new affiliation as a footnote. As all your contribution were made while you were with ACC, I feel that this could be a good compromise.

Best regards,

Sebastian

Dr. Sebastian Hoffmann

seh consulting + services

Stembergring 15

33106 Paderborn

Germany

Ex. 6 - Personal Privacy

www.seh-cs.com

sebastian.hoffmann@seh-cs.com

Von: "Beck, Nancy" <Beck.Nancy@epa.gov>
Datum: 10. Mai 2017 um 13:42:34 MESZ
An: "sebastian.hoffmann@seh-cs.com" <sebastian.hoffmann@seh-cs.com>
Kopie: Katherine Tsaïoun <ktsaiou1@jhu.edu>
Betreff: FW: Primer: update

Sebastian—

Congratulations! This is great news!

As I have a new affiliation (I am now at EPA), I will need to change my contact information and also get clearance. I will work with my General Counsel to sort it out quickly. Do you have a deadline for revisions and changes like this?

Regards,

Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Ex. 6 - Personal Privacy

From: Thayer, Kris

From: Sebastian Hoffmann [<mailto:sebastian.hoffmann@seh-cs.com>]

Sent: Wednesday, May 10, 2017 5:20 AM

To: [Nancy Beck@americanchemistry.com](mailto:Nancy_Beck@americanchemistry.com); Rob de Vries <R.deVries@cdl.umcn.nl>; Martin Stephens <msteph14@jhu.edu>; Dirven, Hubert <Hubert.Dirven@fhi.no>; jackfowle@aol.com; Julie Goodman <JGoodman@gradientcorp.com>; Thomas Hartung <thartun1@jhu.edu>; Ian Kimber <ian.kimber@manchester.ac.uk>; Manoj Lalu <manojlalu@gmail.com>; Thayer, Kris <thayer.kris@epa.gov>; Paul Whaley <p.whaley@lancaster.ac.uk>; Daniele Wikoff <dwikoff@toxstrategies.com>; Katya Tsaioun <ktsaiou1@jhu.edu>

Subject: Re: Primer: update

Dear all,

You may have heard the good news already that our primer on systematic review was accepted as

is!

Thanks a lot again for your contribution!

We are currently in the process of proof reading.

I will keep you updated.

Best regards,

Sebastian

Dr. Sebastian Hoffmann

seh consulting + services

Stembergring 15

33106 Paderborn

Germany

Ex. 6 - Personal Privacy

<ATOX-S-17-00266.pdf>

To: Jain, Komal[Komal_Jain@americanchemistry.com]
From: Beck, Nancy
Sent: Fri 8/4/2017 6:53:13 PM
Subject: RE: hiring?

Ok. definitely send a CV. There is a hiring freeze (unless he wants to be a fellow ☺) so I think political is the most workable.

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Ex. 6 - Personal Privacy

From: Jain, Komal [mailto:Komal_Jain@americanchemistry.com]
Sent: Friday, August 4, 2017 2:45 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: hiring?

He would certainly consider it.

From: Beck, Nancy [mailto:Beck.Nancy@epa.gov]
Sent: Friday, August 4, 2017 2:38 PM
To: Jain, Komal <Komal_Jain@americanchemistry.com>
Subject: RE: hiring?

Hey Komal,

Would he take a political position?

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Ex. 6 - Personal Privacy

From: Jain, Komal [mailto:Komal_Jain@americanchemistry.com]

Sent: Friday, August 4, 2017 2:35 PM

To: Beck, Nancy <Beck.Nancy@epa.gov>

Subject: hiring?

Hi Nancy,

I hope you are doing well. Busy for sure! I'd love to catch up whenever you can clear your calendar for lunch or a cocktail.

I heard through Seth Goldberg that you may be hiring for several positions. I'm not inquiring for myself, but for my husband Craig who has been in the environmental arena for a long time. In fact, he is a former EPA employee; he was with the Energy Star program for several years. He recently left Toshiba where he ran its environmental affairs program for the Americas for 10+ years. He's looking for senior level position in a policy/management role (not a scientist). Anything come to mind? I can shoot his CV over if there is a possibility.

Thanks! And, Happy Friday.

All the best,

Komal

Komal K. Jain, J.D. | American Chemistry Council

Senior Director, Chemical Products & Technology Division

komal_jain@americanchemistry.com

700 2nd Street, NE | Washington, DC | 20002

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+++++ This message may contain confidential information and is intended only for the individual named. If you are not the named addressee do not disseminate, distribute or copy this email. Please notify the sender immediately by email if you have received this email by mistake and delete this email from your system. E-mail transmission cannot be guaranteed to be secure or error-free as information could be intercepted, corrupted, lost, destroyed, arrive late or incomplete, or contain viruses. The sender therefore does not accept liability for any errors or omissions in the contents of this message which arise as a result of email transmission. American Chemistry Council, 700 – 2nd Street NE, Washington, DC 20002, www.americanchemistry.com

+++++ This message may contain confidential information and is intended only for the individual named. If you are not the named addressee do not disseminate, distribute or copy this email. Please notify the sender immediately by email if you have received this email by mistake and delete this email from your system. E-mail transmission cannot be guaranteed to be secure or error-free as information could be intercepted, corrupted, lost, destroyed, arrive late or incomplete, or contain viruses. The sender therefore does not accept liability for any errors or omissions in the contents of this message which arise as a result of email transmission. American Chemistry Council, 700 – 2nd Street NE, Washington, DC 20002, www.americanchemistry.com

To: Jain, Komal[Komal_Jain@americanchemistry.com]
From: Beck, Nancy
Sent: Fri 8/4/2017 6:37:56 PM
Subject: RE: hiring?

Hey Komal,

Would he take a political position?

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Ex. 6 - Personal Privacy

From: Jain, Komal [mailto:Komal_Jain@americanchemistry.com]
Sent: Friday, August 4, 2017 2:35 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: hiring?

Hi Nancy,

I hope you are doing well. Busy for sure! I'd love to catch up whenever you can clear your calendar for lunch or a cocktail.

I heard through Seth Goldberg that you may be hiring for several positions. I'm not inquiring for myself, but for my husband Craig who has been in the environmental arena for a long time. In fact, he is a former EPA employee; he was with the Energy Star program for several years. He recently left Toshiba where he ran its environmental affairs program for the Americas for 10+ years. He's looking for senior level position in a policy/management role (not a scientist).

Anything come to mind? I can shoot his CV over if there is a possibility.

Thanks! And, Happy Friday.

All the best,

Komal

Komal K. Jain, J.D. | American Chemistry Council

Senior Director, Chemical Products & Technology Division

komal_jain@americanchemistry.com

700 2nd Street, NE | Washington, DC | 20002

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+++++ This message may contain confidential information and is intended only for the individual named. If you are not the named addressee do not disseminate, distribute or copy this email. Please notify the sender immediately by email if you have received this email by mistake and delete this email from your system. E-mail transmission cannot be guaranteed to be secure or error-free as information could be intercepted, corrupted, lost, destroyed, arrive late or incomplete, or contain viruses. The sender therefore does not accept liability for any errors or omissions in the contents of this message which arise as a result of email transmission. American Chemistry Council, 700 – 2nd Street NE, Washington, DC 20002, www.americanchemistry.com

To: Schmit, Ryan[schmit.ryan@epa.gov]
Cc: Cleland-Hamnett, Wendy[Cleland-Hamnett.Wendy@epa.gov]
From: Beck, Nancy
Sent: Mon 6/5/2017 10:12:24 PM
Subject: FW: In Print---1,4-Dioxane Publication
[E1E8A4B9-00D9-4B4E-B4FF-FD948FB9EF92\[2\].jpg](#)

Ryan,

Can you get this to the right folks?

Thanks!

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Ex. 6 - Personal Privacy

beck.nancy@epa.gov

From: Dourson, Michael (doursoml) [mailto:doursoml@ucmail.uc.edu]
Sent: Monday, June 5, 2017 6:09 PM
To: Akihiko Hirose <akihikoh@dranihs.net>; rhryuichihasegawa08@gmail.com; 'Michael L. Caldwell' <MCaldwell@zacfirm.com>; Beck, Nancy <Beck.Nancy@epa.gov>; Birchfield, Norman <Birchfield.Norman@epa.gov>; yamazaki <k-yamazaki@jisha.or.jp>; kmdilwali@intsci.com; 'Michael L. Caldwell' <MCaldwell@zacfirm.com>; Pierre_Therriault@hc-sc.gc.ca; Richard Charron <Richard.Charron@hc-sc.gc.ca>; Sams, Reeder <Sams.Reeder@epa.gov>; mhoneycu@tceq.state.tx.us; Deshpande, Satish (MOECC) <Satish.Deshpande@ontario.ca>; sarah.labib@canada.ca; Shannon Ethridge <sethridg@tceq.state.tx.us>; Barbara Sassi <barbara.sassi@health.mo.gov>; dennis.wambuguh@health.mo.gov; Chris Prucha <cprucha@wm.com>; h-kano@jisha.or.jp; Maier, Michael (maierma) <maierma@ucmail.uc.edu>; t-kasai@jisha.or.jp; sethridg@tceq.state.tx.us; Robert Maronpot <maronpot@me.com>; Whalan, John <Whalan.John@epa.gov>; James E. Klaunig <jklauni@indiana.edu>; Jayne Wright <jayne@jaynewright.co.uk>; Nadine Weinberg <nadine.weinberg@erm.com>; Garoutte, Jonathan <Jonathan.Garoutte@health.mo.gov>; flagac@michigan.gov;

Joseph.Haney@tceq.texas.gov; Phelka, Amanda <aphelka@nsf.org>; jenglish@nsf.org; Laessig, Susan <Laessig.Susan@epa.gov>; Herbert, Ron (NIH/NIEHS) [E] <herbert@niehs.nih.gov>; oono-yurie@mhlw.go.jp; toxpathmcc <toxpathmcc@bellsouth.net>; Jeff.Wenzel@health.mo.gov; Maria Hegstad <mhegstad@iwpnews.com>; Doug Wolf <Wolf.Doug@epamail.epa.gov>; helen.goeden@state.mn.us; James.kelly@state.mn.us; Franz, Christina <Christina_Franz@americanchemistry.com>; Kylie Brockenfelt <KBrockenfelt@epl-inc.com>; riesd@michigan.gov; 'Sager, Shawn' <Shawn.Sager@arcadis.com>; HOWARD, WILLIAM B GS-13 USAF AFMC AFCEC/CZTE <william.howard.40@us.af.mil>; Hamlin, Mel (NIH/NIEHS) [C] (hamlin@niehs.nih.gov) <hamlin@niehs.nih.gov>; ruckner@rx.uga.edu; Harvey Clewell <HClewell@thehamner.org>; david_dorman@ncsu.edu; fjmiller@nc.rr.com; rpsharma@uga.edu; Vandenberg, John <Vandenberg.John@epa.gov>
Cc: Jeri.Higginbotham@ky.gov; jcrum@hampmathews.com; burleighflayer@ppg.com; Nance, Patricia (nancepm) <nancepm@ucmail.uc.edu>; 'Forsberg, Norman' <Norman.Forsberg@arcadis.com>; 'Mark Lafronconi' <Mark.Lafronconi@erm.com>; Reichard, John (reichajf) <reichajf@ucmail.uc.edu>
Subject: In Print---1,4-Dioxane Publication

Dear Colleagues

On behalf of the authors, I am pleased to let you know that our publication is now in print as shown below. The paper was developed under the umbrella of the Alliance for Risk Assessment (ARA), and is open access thanks to Norm Forsberg and his company Arcadis. Please feel free to share this paper as needed.

Cheers!

Michael Dourson

— *Risk Science Center (formerly TERA Center) sponsors the International Toxicity Estimates for Risk (ITER) database of risk assessment values on Toxnet: <http://toxnet.nlm.nih.gov/>*



From: RSS Feed via IFTTT <weeklydigest@ifttt.com>

Date: Monday, June 5, 2017 at 8:14 AM

To: Michael Dourson <doursoml@ucmail.uc.edu>

Subject: Weekly Digest: If new feed item

from <http://rss.sciencedirect.com/publication/science/02732300>, then add to weekly digest sent to michael.dourson@uc.edu on (7 items)

Update: Mode of action (MOA) for liver tumors induced by oral exposure to 1,4-dioxane

Publication date: August 2017

Source: Regulatory Toxicology and Pharmacology, Volume 88

Author(s): Michael L. Dourson, Jeri Higginbotham, Jeff Crum, Heather Burleigh-Flayer, Patricia Nance, Norman D. Forsberg, Mark Lafranconi, John Reichard

Previous work has shown that the weight of evidence supports the hypothesis that 1,4-dioxane causes liver tumors in rodents through cytotoxicity and subsequent regenerative hyperplasia. Questions regarding a lack of concordant findings for this mode of action (MOA) in mice have not been resolved, however. In the current work, a reanalysis of data from two chronic mouse cancer bioassays on 1,4-dioxane, one 13-week mouse study, seven rat cancer bioassays, coupled with other data such as 1,4-dioxane's negative mutagenicity, its lack of up-regulated DNA repair, and the appearance of liver tumors with a high background incidence, support the conclusion that rodent liver tumors, including those in mice, are evoked by a regenerative hyperplasia MOA. The initiating event for this MOA is metabolic saturation of 1,4-dioxane. Above metabolic saturation, higher doses of the parent compound cause an ever increasing toxicity in the rodent liver as evidenced by higher blood levels of enzymes indicative of liver cell damage and associated histopathology that occurs in a dose and time related manner. Importantly, alternative modes of action can be excluded. The observed liver toxicity has a threshold in the dose scale at or below levels that saturate metabolism, and generally in the range of 9.6–42 mg/kg-day for rats and 57 to 66 mg/kg-day for mice. It follows that threshold approaches to the assessment of this chemical's toxicity are supported by the non-mutagenic, metabolic saturation kinetics, and cytotoxicity-generated regenerative repair information available for 1,4-dioxane promoted rodent liver tumors.

via ScienceDirect Publication: Regulatory Toxicology and

Pharmacology <http://ift.tt/2r6ix2E> May 30, 2017 at 02:02AM

via RSS

Feed <http://rss.sciencedirect.com/action/redirectFile?&zone=main&Activity=feed&usageType=outward>

From: Michael Dourson <doursoml@ucmail.uc.edu>

Date: Thursday, February 23, 2017 at 2:28 PM

To: Akihiko Hirose <akihikoh@dranihs.net>, "rhryuichihasegawa08@gmail.com" <rhryuichihasegawa08@gmail.com>, "Michael L. Caldwell" <MCaldwell@zacfirm.com>, "Beck, Nancy" <Nancy_Beck@americanchemistry.com>, "Birchfield, Norman" <Birchfield.Norman@epa.gov>, yamazaki <k-yamazaki@jisha.or.jp>, "kmdilwali@intsci.com" <kmdilwali@intsci.com>, "Michael L. Caldwell" <MCaldwell@zacfirm.com>, "Pierre_Therriault@hc-sc.gc.ca" <Pierre_Therriault@hc-sc.gc.ca>, Richard Charron <Richard.Charron@hc-sc.gc.ca>, "Sams, Reeder" <Sams.Reeder@epa.gov>, Michael Honeycutt <MHoneycu@tceq.state.tx.us>, "Deshpande, Satish (MOECC)" <Satish.Deshpande@ontario.ca>, "Labib, Sarah (HC/SC)" <sarah.labib@canada.ca>, Shannon Ethridge <sethridg@tceq.state.tx.us>, Barbara Sassi <barbara.sassi@health.mo.gov>, Dennis Wambuguh <dennis.wambuguh@health.mo.gov>, Chris Prucha <cprucha@wm.com>, "h-kano@jisha.or.jp" <h-kano@jisha.or.jp>, Andy Maier <maierma@ucmail.uc.edu>, "t-kasai@jisha.or.jp" <t-kasai@jisha.or.jp>, "sethridg@tceq.state.tx.us" <sethridg@tceq.state.tx.us>, Robert Maronpot <maronpot@me.com>, "Whalan, John" <Whalan.John@epa.gov>, "Klaunig, James E." <jklauni@indiana.edu>, Jayne Wright <jayne@jaynewright.co.uk>, Nadine Weinberg <nadine.weinberg@erm.com>, "Garoutte, Jonathan" <Jonathan.Garoutte@health.mo.gov>, "Flaga, Christine (DEQ)" <FLAGAC@michigan.gov>, "Joseph.Haney@tceq.texas.gov" <Joseph.Haney@tceq.texas.gov>, "Phelka, Amanda" <aphelka@nsf.org>, "English, Joanne Caroline" <jenglish@nsf.org>, "Laessig, Susan" <Laessig.Susan@epa.gov>, "Herbert, Ron (NIH/NIEHS) [E]" <herbert@niehs.nih.gov>, "oono-yurie@mhlw.go.jp" <oono-yurie@mhlw.go.jp>, toxpathmcc <toxpathmcc@bellsouth.net>, "Jeff.Wenzel@health.mo.gov" <Jeff.Wenzel@health.mo.gov>, Maria Hegstad <mhegstad@iwpnews.com>, Doug Wolf <Wolf.Doug@epamail.epa.gov>, "Goeden, Helen (MDH)" <Helen.Goeden@state.mn.us>, "Kelly, James (MDH)" <james.kelly@state.mn.us>, "Franz, Christina" <Christina_Franz@americanchemistry.com>, Kylie Brockenfelt <KBrockenfelt@epl-inc.com>, "Ries, Divinia (DEQ)" <RIESD@michigan.gov>, "Sager, Shawn" <Shawn.Sager@arcadis.com>, "HOWARD, WILLIAM B GS-13 USAF AFMC AFCEC/CZTE" <william.howard.40@us.af.mil>, "Hamlin, Mel (NIH/NIEHS) [C]" <hamlin@niehs.nih.gov>, "ruckner@rx.uga.edu" <ruckner@rx.uga.edu>, Harvey Clewell <HClewell@thehamner.org>, "david_dorman@ncsu.edu" <david_dorman@ncsu.edu>, "fjmiller@nc.rr.com" <fjmiller@nc.rr.com>, "rpsharma@uga.edu" <rpsharma@uga.edu>, John Vandenberg <Vandenberg.John@epamail.epa.gov>

Cc: "Higginbotham, Jeri ' (EEC)" <Jeri.Higginbotham@ky.gov>, "jcrum@hampmathews.com" <jcrum@hampmathews.com>, "Burleigh-Flayer, Heather" <burleighflayer@ppg.com>, Patricia Nance <nancepm@ucmail.uc.edu>, "Forsberg, Norman" <Norman.Forsberg@arcadis.com>, 'Mark Lafranchi' <Mark.Lafranchi@erm.com>

Subject: Accepted 1,4-Dioxane Publication

Dear Colleagues

On behalf of the authors listed in the CC section of this email, it gives me great pleasure to state that a manuscript entitled "Update: Mode of Action (MOA) for Liver Tumors Induced by Oral Exposure to 1,4-Dioxane" has been accepted by Regulatory Toxicology and Pharmacology. An abstract is found below.

This work was conducted under the auspices of the Alliance for Risk Assessment (*ARA*), and involved multiple groups acting collaboratively. Updates of this accepted text prior to it being published will be posted on the Alliance for Risk Assessment (*ARA*) website, specifically, <http://allianceforrisk.org/14-dioxane-analysis>.

Please feel free to let your colleagues know as well.

Sincerely,

A handwritten signature in dark ink, appearing to read "Michael L. Dourson", is positioned above the typed name.

Michael L. Dourson, Ph.D., DABT, FATS, FSRA
Professor

Risk Science Center (formerly TERA)

Department of Environmental Health
University of Cincinnati, College of Medicine
160 Panzeca Way

Ex. 6 - Personal Privacy

<http://eh.uc.edu/tera/>



Abstract

Previous scientific studies show that the weight of evidence supports the hypothesis that 1,4-dioxane causes liver tumors in rodents through cytotoxicity and subsequent regenerative hyperplasia. Questions regarding a lack of concordant findings for this mode of action (MOA) in mice have not been resolved, however. In the current work, a reanalysis of data from two chronic mouse cancer bioassays on 1,4-dioxane, one 13-week mouse study, seven rat cancer bioassays, coupled with other data demonstrating negative mutagenicity, lack of up-regulated DNA repair, and the appearance of liver tumors with a high background incidence, support the conclusion that rodent liver tumors, including those in mice, are evoked by a regenerative hyperplasia MOA. The initiating event for this MOA is metabolic saturation of 1,4-dioxane. Above metabolic saturation, higher doses of the parent compound cause an ever increasing toxicity in the rodent liver as evidenced by higher blood levels of enzymes indicative of liver cell damage and associated histopathology that occurs in a dose and time related manner. Importantly, alternative modes of action can be excluded. The observed liver toxicity has a threshold in the dose scale at or below levels that saturate metabolism, and generally in the range of 9.6 to 42 mg/kg-day for rats and 57 to 66 mg/kg-day for mice. It follows that threshold approaches to the assessment of this chemical's toxicity are supported by the non-mutagenic, metabolic saturation kinetics, and cytotoxicity-generated regenerative repair information available for 1,4-dioxane promoted rodent liver tumors.

From: eesserver@eesmail.elsevier.com [<mailto:eesserver@eesmail.elsevier.com>]

Sent: Thursday, February 23, 2017 10:33 AM

To: Nance, Patricia (nancepm) <nancepm@ucmail.uc.edu>; pnance1972@gmail.com

Subject: RTP-16-335R2: Final Decision

Ms. No.: RTP-16-335R2

Title: Update: Mode of Action (MOA) for Liver Tumors Induced by Oral Exposure to 1,4-Dioxane

Corresponding Author: Ms. Patricia Nance

Authors: Michael Dourson; Jeri Higginbotham; Jeff Crum; Heather Burleigh-Flayer; Norman Forsberg; Mark Lafranconi

Dear Ms. Nance,

Congratulations. I am pleased to inform you that your manuscript, referenced above, has been accepted for publication in Regulatory Toxicology and Pharmacology.

Many thanks for this paper. We look forward to the submission of your future manuscripts to Regulatory Toxicology and Pharmacology.

Your accepted manuscript will now be transferred to our production department and work will begin on creation of the proof. If we need any additional information to create the proof, we will let you know. If not, you will be contacted again in the next few days with a request to approve the proof and to complete a number of online forms that are required for publication.

When your paper is published on ScienceDirect, you want to make sure it gets the attention it deserves. To help you get your message across, Elsevier has developed a new, free service called AudioSlides: brief, webcast-style presentations that are shown (publicly available) next to your published article. This format gives you the opportunity to explain your research in your own words and attract interest. You will receive an invitation email to create an AudioSlides presentation shortly. For more information and examples, please visit <http://www.elsevier.com/audioslides>.

With kind regards,

Dr. Gio Batta Gori, Editor-in-Chief
Regulatory Toxicology and Pharmacology
E-mail: rtp@elsevier.com

To: Goldstein, Bernard D[bdgold@pitt.edu]
From: Beck, Nancy
Sent: Wed 5/31/2017 8:47:59 PM
Subject: RE: Follow-up on SRA Session

Bernie,

I'm not seeing the proposal.

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Ex. 6 - Personal Privacy

From: Goldstein, Bernard D [mailto:bdgold@pitt.edu]
Sent: Wednesday, May 31, 2017 3:12 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: Follow-up on SRA Session

Hi Nancy

Most recent version of proposal is below. The five speakers for 10 min each in alphabetical order are Arvai, Beck, Denison, Goldstein and White. I need to get this in by **tonight**

Also – would you like to be listed with a middle initial?

Thanks again for doing this

Bernie

From: Beck, Nancy [<mailto:Beck.Nancy@epa.gov>]
Sent: Monday, May 22, 2017 6:49 PM
To: Goldstein, Bernard D <bdgold@pitt.edu>
Subject: RE: Follow-up on SRA Session

Got it. When you have a final abstract send it my way and I'll take a look.

It is a bit awkward.. I think I can be on a panel with them, but do not want to be collaborating with them, or even seen as collaborating with them.

Nancy B. Beck, Ph.D., DABT

~~Deputy Assistant Administrator, OCSPP~~

Ex. 6 - Personal Privacy

From: Goldstein, Bernard D [<mailto:bdgold@pitt.edu>]
Sent: Monday, May 22, 2017 3:52 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: Follow-up on SRA Session

Sorry to be unclear. I do need names for the submission, but do not need your participation in the preparation of the abstract. I apologize, as I should have realized that this might be a problem for you

Needless to say, you could withdraw at any time.

Bernie

From: Beck, Nancy [<mailto:Beck.Nancy@epa.gov>]
Sent: Monday, May 22, 2017 7:42 AM
To: Goldstein, Bernard D <bdgold@pitt.edu>
Subject: RE: Follow-up on SRA Session

Bernie,

As I am recused from interactions with ACC, it's a bit awkward for me to be planning a session with them.

As you said you don't need names just yet for the submission, why don't you just move ahead without me and let's circle back in the fall to see if it makes sense for me to join the panel.

Regards,

Nancy

Nancy B. Beck, Ph.D., DABT

Deputy Assistant Administrator, OCSPP

Ex. 6 - Personal Privacy

Ex. 6 - Personal Privacy

beck.nancy@epa.gov

From: Goldstein, Bernard D [<mailto:bdgold@pitt.edu>]
Sent: Monday, May 22, 2017 5:24 AM
To: White, Kimberly <Kimberly_White@americanchemistry.com>
Cc: Rick Becker<Rick_Becker@americanchemistry.com>; Joe Arvai <jlarvai@umich.edu>; Beck, Nancy <Beck.Nancy@epa.gov>
Subject: RE: Follow-up on SRA Session

Hi Kimberly

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Bernie

Bernard D. Goldstein, MD

Professor Emeritus and Dean Emeritus

University of Pittsburgh Graduate School of Public Health

130 Desoto St; Rm A-710

Pittsburgh PA 15261

Ex. 6 - Personal Privacy

From: White, Kimberly [mailto:Kimberly_White@americanchemistry.com]

Sent: Friday, May 19, 2017 6:22 PM

To: Goldstein, Bernard D <bdgold@pitt.edu>

Cc: Becker, Rick <Rick_Becker@americanchemistry.com>

Subject: RE: Follow-up on SRA Session

Dear Bernie:

Thanks for the additional information about the session and the abstract. We offer some suggestions to

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Kimberly Wise White, Ph.D. | American Chemistry Council

Senior Director, Chemical Products & Technology Division

Kimberly_White@americanchemistry.com

700 2nd Street NE | Washington, DC | 20002

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Dear Dr White

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Phone 412 648 9994

From: Goldstein, Bernard D
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Sent from my iPhone

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To: Goldstein, Bernard D[bdgold@pitt.edu]
From: Beck, Nancy
Sent: Mon 5/22/2017 11:42:20 AM
Subject: RE: Follow-up on SRA Session

Bernie,

As I am recused from interactions with ACC, it's a bit awkward for me to be planning a session with them.

As you said you don't need names just yet for the submission, why don't you just move ahead without me and let's circle back in the fall to see if it makes sense for me to join the panel.

Regards,

Nancy

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To: Dourson, Michael (doursoml)[doursoml@ucmail.uc.edu]
From: Beck, Nancy
Sent: Fri 5/12/2017 6:05:23 PM
Subject: RE: Offered symposium

Mike,

I need to be very careful about blurring lines between ACC and EPA. Not to mention clearance processes. Based on my learnings it would be highly unlikely that I would ever get clearance to do a presentation on work that I conducted at ACC. Even more sensitivity if its during the first year. Thus I will have to back out of this.

Bill Farland, Lynn Pottenger, or Jeff Lewis could do this well (and yourself as well....).

Nancy

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Deputy Assistant Administrator, OCSPP

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beck.nancy@epa.gov

From: Dourson, Michael (doursoml) [mailto:doursoml@ucmail.uc.edu]
Sent: Friday, May 12, 2017 12:33 PM
To: Beck, Nancy <Beck.Nancy@epa.gov>
Subject: FW: Offered symposium

Nancy

Sorry to miss your email the first time...

Cheers!

Michael...

...L. Dourson, Ph.D., DABT, FATS, FSRA

Professor

Risk Science Center (formerly TERA)

Department of Environmental Health
University of Cincinnati, College of Medicine
160 Panzeca Way
Cincinnati OH 45267-0056

Ex. 6 - Personal Privacy

<http://eh.uc.edu/tera/>



From: Michael Dourson <doursoml@ucmail.uc.edu>

Date: Friday, May 12, 2017 at 12:26 PM

To: Edward Calabrese <edwardc@schoolph.umass.edu>, "nancy.beck@epa.gov" <nancy.beck@epa.gov>, Daniel Krewski <dkrewski@uottawa.ca>, "Manibusan, Mary" <mmanibusan@exponent.com>, "Becker, Rick" <Rick_Becker@americanchemistry.com>, KASS Georges <Georges.KASS@efsa.europa.eu>

Cc: "Fitzpatrick, Suzanne" <Suzanne.Fitzpatrick@fda.hhs.gov>

Subject: FW: Offered symposium

Dear Colleagues

Please find attached a developing draft of a to-be-submitted symposium for next year's Society of Toxicology annual meeting. Your thoughts on individual abstracts and overall descriptions are most welcome. We will be formally submitting this next week early, so comments by this Sunday evening are needed.

Cheers!

Michael

— *Risk Science Center (formerly TERA Center) sponsors the International Toxicity Estimates for Risk (ITER) database of risk assessment values on Toxnet: <http://toxnet.nlm.nih.gov/>*



From: Michael Dourson <doursoml@ucmail.uc.edu>
Date: Friday, May 12, 2017 at 12:21 PM
To: Elizabeth Vancza <elizabeth.vancza@safebridge.com>
Cc: "Fitzpatrick, Suzanne" <Suzanne.Fitzpatrick@fda.hhs.gov>, "Ohanian, Edward" <Ohanian.Edward@epa.gov>, "marie.c.fortin@gmail.com" <marie.c.fortin@gmail.com>
Subject: Offered symposium

Dear Liz

I so much apologize for this late breaking symposium. Needless to say, we would highly value your committee's thoughts on this prior to the deadline of next Monday (or so). We completely understand if your group is not able to turn this around.

Cheers!

Michael

-- *If you can't explain it simply, you don't understand it well enough. Albert Einstein*

